Complete Summary

GUIDELINE TITLE

Procedure guideline for pediatric sedation in nuclear medicine.

BIBLIOGRAPHIC SOURCE(S)

Mandell GA, Majd M, Shalaby-Rana EI, Gordon I. Procedure guideline for pediatric sedation in nuclear medicine, 3.0. Reston (VA): Society of Nuclear Medicine; 2003 Jan 25. 5 p. [14 references]

GUIDELINE STATUS

This is the current release of the guideline.

The guideline updates a previous version: Society of Nuclear Medicine. Procedure guideline for pediatric sedation in nuclear medicine, 2.0. Reston (VA): Society of Nuclear Medicine; 1999 Feb. 15 p.(Society of Nuclear Medicine procedure guidelines; no. 2.0).

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On April 25, 2005 the U.S. Food and Drug Administrations (FDA) notified healthcare professionals and patients that cases of breathing problems, some causing death, have been reported to the FDA when Promethazine HCl (marketed as Phenergan) was used in children less than two years old. Parents and caregivers should also be careful and get a doctor's advice about giving promethazine HCl in any form to children age two and older. The labeling on all products, brand name and generic, has been changed to reflect these strengthened warnings. See the FDA Web site for more information.

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SCOPE

DISEASE/CONDITION(S)

Pediatric conditions for which nuclear medicine studies are indicated

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Anesthesiology
Nuclear Medicine
Pediatrics
Radiology

INTENDED USERS

Allied Health Personnel
Physicians

GUIDELINE OBJECTIVE(S)

To provide assistance to those institutions without pediatric sedation guidelines for nuclear medicine procedures already in place

TARGET POPULATION

Children undergoing nuclear medicine procedures who require sedation

INTERVENTIONS AND PRACTICES CONSIDERED

1. Conscious sedation
2. Deep sedation
3. General anesthesia

MAJOR OUTCOMES CONSIDERED

Risks, benefits, safety, and utility of pediatric sedation in nuclear medicine

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were performed. In addition, references known to experts and references from the nuclear medicine community were considered.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Drafts of the guideline were submitted to members of the Guideline Development subcommittee (methodologists) and the Task Force (subject experts). These reviewers indicated on a line-by-line basis any suggestions or recommendations for the revision of the guideline. The percentage of agreement for all reviewers was calculated for each revision and compiled by the Society of Nuclear Medicine (SNM) central office. It is expected that the percentage of agreement will increase with each revision.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When the Task Force and Guideline Development Subcommittee completed their edits, draft procedure guidelines were distributed to the Society of Nuclear Medicine (SNM) Sample Review Group for comment. (The SNM Sample Review Group is a cross-section of approximately 100 nuclear medicine practitioners representing every field of specialization).

The guideline was approved by the SNM Commission on Health Care Policy, the Board of Directors, and the House of Delegates.

The updated guideline was approved January 25th, 2003.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions

Sedation is a medically controlled state of depressed consciousness or unconsciousness. Sedation can be divided into conscious sedation, deep sedation, and general anesthesia. In conscious sedation, the patient maintains the ability to respond to external stimulation. In deep sedation, patients are not easily aroused. In general anesthesia, patients are not arousable by stimulation.

The important clinical distinction between these states revolves around the ability of the patient to maintain his or her protective reflexes. The consciously sedated patient maintains protective reflexes, such as gagging and swallowing, and therefore can keep his or her airway patent without assistance. The deeply sedated patient may lose these reflexes and may not be able to maintain his or her airway. The patient under general anesthesia has lost protective reflexes and is unable to maintain his or her airway.

There are no sharp boundaries between conscious sedation, deep sedation, and general anesthesia. Furthermore, patients may rapidly move from conscious sedation through deep sedation to general anesthesia. Therefore, clinics that

sedate children must be prepared to manage all levels of sedation and general anesthesia, even if only conscious sedation is intended.

Published Rules Concerning Pediatric Sedation

The Joint Commission on Accreditation of Health Care Organizations mandates an institution-wide policy for pediatric sedation. It is advisable to follow each institution's established sedation policy, if such a policy exists. Guidelines for the monitoring and sedation of children are published by the American Academy of Pediatrics (AAP). These guidelines are quite extensive and include documentation, informed consent, patient preparation, pre-sedation evaluation, monitoring, post-sedation care, discharge criteria, and instructions, as well as follow-up (see addendum #1 in the original guideline document).

Appropriate Personnel and Equipment

Safe sedation requires an appropriately trained individual (ATI) with experience and training in pediatric sedation, pediatric airway maintenance, and pediatric advanced life support (PALS). The ATI not only explains the sedation procedure to the family, but screens the child for negative outcome factors, such as significant upper airway obstruction, apnea, reactive airway disease, risk for vomiting and aspiration, and uncontrolled seizures. A consultation with a pediatric anesthesiologist or intensivist about a child with risk factors may be necessary before the sedation procedure.

An emergency cart with equipment and drugs suitable for children of all ages and sizes should be readily available. Functioning suction apparatus with appropriate suction catheters, as well as positive-pressure oxygen delivery system capable of administering greater than 90% oxygen, are also mandatory. The ATI continually monitors the patient with a pulse oximeter throughout the procedure. The patient is monitored until awakening and the institution's discharge criteria are met.

Avoidance of Sedation

For many pediatric nuclear procedures, sedation and its attendant risks are avoidable by having an attentive and caring approach to children. The pain of most nuclear medicine procedures is limited to a single venipuncture or catheterization of the bladder. For patients in whom the pain of venipuncture is a limiting factor, topical lidocaine preparations are available. These are best used one to two hours before injection. They may be prescribed before the procedure and applied by a parent at home before arriving in the nuclear medicine clinic. Xylocaine jelly can be used for difficult urethral catheterizations (particularly in males). Giving full information about the examination to the parents and child at the time the appointment is made reduces anxiety levels in both parents and child.

Many nonpharmacologic strategies are available to help the child cooperate and hold still during a nuclear medicine exam. Cooperation can be maximized in many instances by allowing the parents to be with their child during the examination and letting the child have the comfort of a pacifier, bottle, blanket, or stuffed animal. Depending on the age of the child, a reassuring description of the procedure can be provided before and during the procedure by a technologist who

has a good rapport with children. The room can be decorated to make it more interesting and comfortable for the child. The distraction of a child's attention by reading of a story or viewing television or a VCR allows reduction of patient motion. Parents can be instructed to schedule the procedure during the younger child's nap time to maximize the chances that he or she will sleep during the procedure. In addition, a "papoose," sandbags, or adhesive tape can be used to restrain infants and younger children. Use of these strategies can avoid sedation while allowing acquisition of quality images.

Choosing A Sedation Regimen

Sedation regimens vary greatly from one institution to another and even among physicians in the same department. There is no consensus on the best protocol for the sedation of children. The choice of drugs and route of administration depends on the patient's age, history of underlying illness (e.g., mental deficiency, cardiac or respiratory illness), experience and familiarity with certain drugs, institutional protocols, length of procedure, and availability of support (reversal drugs).

In infants and young children, rectally or (more commonly) orally administered drugs are adequate for sedation. Rectal absorption tends to be erratic and the oral method is usually the preferred route of administration. Chloral hydrate is commonly used in infants and young children (usually up to 15 kg) and is recommended by the American Academy of Pediatrics (AAP) as an "effective sedative with a low incidence of acute toxicity when administered orally in the recommended dosage for short-term sedation." Chloral hydrate in a dose of 50 to 70 mg/kg (maximum total accumulated dose of 100 mg/kg) is usually adequate to achieve sedation. The maximum total dose varies according to the guidelines of the individual institution.

In older patients and children with mental deficiency, parenteral sedation, usually intravenous, may be the preferred method. Intravenous sedation allows for rapid induction and recovery, with better scheduling of sedation cases during high volume periods. However, intravenous sedation must be titrated for each patient, using the recommended dosage range.

Pentobarbital sodium (Nembutal) is popular because it is a short acting barbiturate with low incidence of respiratory depression. It is commonly used in dosages of 2 to 6 mg/kg. The maximum dosage varies according to the guidelines of the individual institution. Nembutal is contraindicated in patients with porphyria and may require higher doses in patients being treated for a seizure disorder. Versed is often coupled with Nembutal in doses of 0.1 mg/kg intravenously, for a maximum total dose of 2.5 mg. Other intravenous sedation regimens (opiates and benzodiazepines) are used less frequently in the pediatric population. Reversal drugs are required to treat overdoses, such as naloxone (Narcan) for opiates and flumazenil (Romazicon) for benzodiazepines.

Classes of drugs used for parenteral sedation: Dosages vary and can be generated by the pediatric anesthesiology or critical care section of the individual institution.

- Barbiturates including pentobarbital sodium (Nembutal)
- Opiates including meperidine (Demerol) and fentanyl (Sublimaze)
- Benzodiazepines including diazepam (Valium) and midazolam (Versed)

- Phenothiazines including chlorpromazine (Thorazine) and Promethazine (Phenergan)
- Neuroleptic agents including ketamine (Ketalar)

Sedation protocols use drugs singly or in combination. The use of analgesic opiates, such as fentanyl and meperidine (as part of DPT--Demerol, Phenergan, and Thorazine), is rarely necessary for most nuclear medicine procedures. Also, opiates may cause respiratory depression, especially if administered rapidly. Ketamine can cause hallucinations in older children.

Midazolam can be used alone or as an adjunct with other sedation drugs, such as opiates and barbiturates, and may be used orally, intravenously, rectally, or intranasally. Recently, there is a growing enthusiasm for the use of intranasal midazolam with its predominantly amnestic effect in children undergoing pre-anesthetic sedation, echocardiography, and short surgical procedures. Nasally administered midazolam in a dose of 0.2 mg/kg has been shown to have very minimal respiratory depression and a relatively short duration of sedation, approximately 35 to 45 minutes. Orally administered midazolam in a dose of 0.5 to 0.75mg/kg is available in flavored syrup. Although the rate of absorption is slower than intranasally administered midazolam, the unpleasantness of the nasal drops is avoided and, in general, the oral form is better accepted by patients. It obviates the need for intravenous access and may be suited for some nuclear medicine procedures. It also has a predominantly amnestic effect in children undergoing pre-anesthetic sedation, echocardiography, urethral catheterization, and short surgical procedures. The exact dosages and preferred routes of administration should be ascertained from the guidelines of the individual institution.

The nuclear medicine physician should consult with the anesthesiology department in each institution for specific recommendations on dosages and combinations of sedative drugs. Consultation with an anesthesiologist is particularly important in patients with a history of significant snoring, abnormal airway (i.e., micrognathia), congenital heart disease, reactive airways disease, and increased intracranial pressure.

Developing A Sedation Policy

A written pediatric sedation policy is strongly recommended. The policy should follow institution-wide policy for pediatric sedation and also follow the guidelines of the American Academy of Pediatrics. Many institutions have sedation committees with representation from anesthesiology, nursing, intensive care, pediatrics, and pediatric imaging. This committee can serve as a source of information for the development of the sedation policy in nuclear medicine.

Written medication protocols for sedation are also strongly recommended. Many sedation protocols are available for pediatric sedation, not all of which are appropriate for nuclear imaging procedures. The exact protocol or set of protocols should be tailored to the age of the patient, the pain or discomfort level of the procedure, the length of the imaging procedure, and most important, the experience of physicians in each clinic. The best source of specific sedation protocols is likely to be the institution's anesthesiologist or intensivist, or preferably, pediatric anesthesiologist or pediatric intensivist. These individuals

should have the greatest experience in sedation and should know the latest information on various sedation methods.

The American Academy of Pediatrics recommends that written informed consent be obtained from parents according to each institution's protocol. Consultation with the institution's legal counsel may be helpful to determine guidelines for obtaining such consent.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

There are several uses of sedation in nuclear medicine. First, some procedures, such as single photon emission computed tomography (SPECT) or high-resolution pinhole imaging, require that the child remain absolutely still for extended periods of time. Sedation can reduce patient motion during these prolonged image acquisitions. The second use of sedation is to allow performance of a procedure that requires cooperation of an older child who refuses to cooperate. Typically, patients in this group have an exaggerated fear of the procedure because of a developmental disability, previous health care experiences, or a traumatic experience, such as physical or sexual abuse. Third, patient sedation can also enhance patient care by minimizing discomfort. These recommendations provide suggestions on how to use sedation to maximize the quality of imaging procedures while minimizing the risks.

POTENTIAL HARMS

The risks of sedation include hypoventilation, apnea, airway obstruction, cardiopulmonary arrest, and the morbidity and mortality associated with these events. Obtaining a medical history, including allergies, as well as appropriate personnel and equipment, reduces the likelihood of such untoward events. The providers of sedation must be able to recognize these risks and rapidly respond with appropriate and effective treatment. The decision to sedate the child must involve a careful comparison of the risks and the benefits. The patient should be assessed by the physician supervising the sedation and assigned an American Society of Anesthesiologists (ASA) classification. If the patient is assigned an ASA classification of 3 or more, then this patient should probably be sedated by the anesthesiologist.

CONTRAINDICATIONS

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Nembutal is contraindicated in patients with porphyria and may require higher doses in patients being treated for seizure disorders.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.
- Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.
- These recommendations for sedation of selected children undergoing nuclear medicine procedures are generated to provide assistance to those institutions without pediatric sedation guidelines already in place and are not intended to replace satisfactory existing policies. Sedation is no substitution for adequate child and parent preparation. Friendly staff geared to children, with sufficient time allocated for each pediatric examination, will reduce the need for sedation with many examinations such as dimercaptosuccinic acid and dynamic renography.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mandell GA, Majd M, Shalaby-Rana EI, Gordon I. Procedure guideline for pediatric sedation in nuclear medicine, 3.0. Reston (VA): Society of Nuclear Medicine; 2003 Jan 25. 5 p. [14 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Feb (revised 2003 Jan 25)

GUIDELINE DEVELOPER(S)

Society of Nuclear Medicine, Inc - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Nuclear Medicine (SNM)

GUIDELINE COMMITTEE

Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

The guideline updates a previous version: Society of Nuclear Medicine. Procedure guideline for pediatric sedation in nuclear medicine, 2.0. Reston (VA): Society of Nuclear Medicine; 1999 Feb. 15 p.(Society of Nuclear Medicine procedure guidelines; no. 2.0).

GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of Nuclear Medicine (SNM) Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Society of Nuclear Medicine. Procedure guideline for guideline development. Reston (VA): Society of Nuclear Medicine; 2001 Jun (version 3.0). Electronic copies: Available from the Society of Nuclear Medicine Web site.
- Society of Nuclear Medicine. Performance and responsibility guidelines for NMT. Reston (VA): Society of Nuclear Medicine; 2003. Electronic copies: Available from the Society of Nuclear Medicine Web site.
- Ambulatory sedation assessment & flow sheet. Addendum #1. Reston (VA): Society of Nuclear Medicine; 2003 Jan 25. 1 p. Electronic copies: Available in the original guideline document from the Society of Nuclear Medicine (SNM) Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-mail: ServiceCenter@snm.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 20, 1999. It was verified by the guideline developer as of August 5, 1999. This NGC summary was updated by ECRI on April 15, 2005. This summary was updated by ECRI on May 31, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Promethazine HCl.

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